IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Plaintiffs, v. WATSON LABORATORIES, INC. – FLORIDA Defendant.	Civil Action No. 11-cv-5989 (FSH/PS)
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. 11-cv-6936 (FSH/PS)
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Plaintiffs, v. RANBAXY, INC. and RANBAXY LABORATORIES LTD., Defendants.	Civil Action No. 12-cv-2474 (FSH/PS)

WARNER CHILCOTT'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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Pursuant to the Court's December 19, 2012 Corrected Tenth Amended Pretrial Scheduling Order, (No. 11-cv-6936, D.I. 119), Plaintiffs Warner Chilcott Company, LLC and Warner Chilcott (US), LLC (collectively, "Warner Chilcott") submit this brief in further support of their proposed claim constructions and in response to the claim construction brief submitted by Defendants Watson Laboratories, Inc.–Florida ("Watson"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Ranbaxy, Inc. and Ranbaxy Laboratories Ltd. ("Ranbaxy") (collectively, "Defendants") regarding the disputed claim terms of Warner Chilcott's U.S. Patent Nos. 7,645,459 ("the '459 patent"), 7,645,460 ("the '460 patent"), and 8,246,989 ("the '989 patent") (collectively, "the patents-in-suit").

I. INTRODUCTION

As to the terms "pharmaceutically effective absorption" and "oral dosage form," the patents-in-suit explicitly define these terms. Warner Chilcott proposes the Court adopt those express definitions. Defendants, on the other hand, propose a definition of "pharmaceutically effective absorption" that deviates from those express definitions and is contrary to Defendant Teva's pre-litigation construction of this phrase. Defendants' construction of "oral dosage form" is inconsistent with its own experts' opinions on the common meaning of this term to a person of skill in the art, which Defendant Watson has stated should control, and improperly seeks to read limitations into the claim.

As to the remaining terms in dispute, "a delayed release mechanism," "an enteric coating which provides for release," "pH dependent enteric coating," "a delayed release mechanism to immediately release the risedronate," "an enteric coating which provides for immediate release," "EDTA," "EDTA or a pharmaceutically acceptable salt thereof," and "pH dependent enteric

coating of the granules," there is much agreement among the parties on the interpretation of these terms. To the extent the parties disagree, this is mainly due to Defendants' attempts to improperly read narrowing limitations into the claims. However, the intrinsic record supports Warner Chilcott's constructions of these terms.

II. ARGUMENT

A. "Pharmaceutically effective absorption" ('459 and '460 Patents, All Asserted Claims)

The '459 and '460 patent specifications expressly define what the claim term "pharmaceutically effective absorption" means:

> The term "pharmaceutically effective absorption" as used herein means an amount of a chelating compound high enough to significantly bind the metal ions and minerals in food but low enough not to significantly alter absorption of the bisphosphonate as compared to absorption in the fasted state. That is, absorption is similar with or without food. Given the high variability of bisphosphonate absorption, fed exposure within about 50% of fasting exposure is expected to be pharmaceutically effective absorption.

(Davis Decl. I, Exh. 1, '459 patent, col. 4, ll. 59-67; Exh. 2, '460 patent, col. 4, l. 64 – col. 5, l. 5).[1] This express definition controls the construction of that term. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Defendants' argument to the contrary—that only includes part of the '459 and '460 patents' definition, i.e., "fed exposure of bisphosphonate within about 50% of fasting exposure"—is incomplete and wrong.

[1] As cited herein, "Davis Decl. I" and "Davis Decl. II" refer to the Declarations of Joshua A. Davis accompanying Warner Chilcott's Opening and Responsive Claim Construction Briefs, respectively. "Patunas Decl." refers to the Declaration of Michael E. Patunas accompanying Defendants' Claim Construction Brief. Also cited are the declarations of Defendants' Dr. John Yates and Dr. Edmund Elder, cited as "Yates Decl." and "Elder Decl.," respectively.

1. Defendants' Proposed Construction Is Incomplete

Defendants argue that the term "pharmaceutically effective absorption" would be understood as referring to the absorption of the active ingredient, i.e., risedronate, from the gastrointestinal tract into the bloodstream as well as a specific level of absorption of risedronate to address the food effect. (Def. Br. at 12-14). The express definition of "pharmaceutically effective absorption" in the '459 and '460 patents includes both of those attributes. But it also includes more, which is left out of Defendants' definition. The proper definition of "pharmaceutically effective absorption" includes within its definition that the chelating agent must be in a sufficient amount "not to significantly alter absorption of the bisphosphonate as compared to absorption in the fasted state," and it provides that the absorption of the bisphosphonate "is similar with or without food." The proposed language suggested by Warner Chilcott makes that clear.

2. The Applicants Did Not Clearly and Unmistakably Disavow or Disclaim the Definition of "pharmaceutically effective absorption" During Prosecution

Defendants' argument that the applicants "disclaimed any meaning other than the one proposed by defendants" during prosecution of the '459 and '460 patents is wrong. (Def. Br. at 14-17). Defendants ignore the clear express definition of "pharmaceutically effective absorption" in the '459 and '460 patents. Defendants instead simply assert that during prosecution of these patents, the applicants limited the definition of this term to "fed exposure of bisphosphonate within about 50% of fasting exposure." Defendants offer no explanation, however, as to how or why those statements purportedly change the express definition of "pharmaceutically effective absorption."

Further, Defendants' reading of the prosecution history is incorrect. As the *Phillips* Court recognized, "because the prosecution history represents an ongoing negotiation between

the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). Thus, prosecution statements only can be used to limit claims where they "***clearly and unambiguously disclaimed or disavowed [any interpretation] during prosecution*** in order to obtain claim allowance." *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003) (emphasis added) (internal quotes omitted).

Defendants nonetheless argue that the term "pharmaceutically effective absorption" should be construed as to mean "fed exposure of bisphosphonate within about 50% of fasting exposure" because during prosecution the applicants made reference to that phrase when they amended their claims to add the phrase "pharmaceutically effective absorption." Nothing in the claim amendments limited the meaning of the term "pharmaceutically effective absorption" in the manner Defendants assert. At most, the statements relied on by Defendants are simply short hand for the entire definition. And, Defendants ignore the statement in the amendments where applicants referred to the entire definition of "pharmaceutically effective absorption": "[a]s used herein, the term 'pharmaceutically effective absorption' is well understood in the art, for example, as described by Applicants in its specification at page 6."[2] (Patunas Decl., Exh. D at WTS0006712, n.1; Exh. E at WTS0007500, n.1). The prosecution histories thus fall well short of establishing an "unequivocal disavowal" as urged by Defendants.

When read properly, and in context of the entire prosecution histories, Warner Chilcott did not clearly or unmistakably disclaim or re-define the meaning of the term "pharmaceutically

[2] Page 6 of the '459 and '460 patent applications each contain the entire definition of the phrase "pharmaceutically effective absorption." (*See, e.g.*, Patunas Decl., Exh. D at WTS0005575, ll. 25-30; Exh. E at WTS0006860, ll. 30-35).

effective absorption" from that in the specifications. *See SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005) ("There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term.").

3. Defendants' Extrinsic Evidence Is Entitled to No Weight

Defendants' reliance on extrinsic evidence, through the declaration of its expert, Dr. John Yates, is entitled to no weight.[3] As the *Phillips* Court cautioned, in general, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Phillips*, 415 F.3d at 1318. In particular, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court," and "a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" *Id.* (internal citation omitted). Moreover, "[e]xtrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id*. That is clearly the case here.

This is shown by the fact that Teva itself previously construed this term in the same manner as Warner Chilcott does here. Prior to the litigation, Defendant Teva, as required by the Hatch-Waxman provisions, provided Warner Chilcott with a Notice Letter containing Teva's purported reasons why it believes the '459 and '460 patents are invalid, unenforceable, or would not be infringed. As part of its analysis, Teva provided a discussion of how the term "pharmaceutically effective absorption" should be construed. Starting with the premise that the

[3] Nearly all of Dr. Yates' income in 2010-12 (about 90%) has been from acting as a paid consultant for generic companies in various ANDA litigations challenging bisphosphonate patents. (Davis Decl. II, Exh. 9, Yates Tr. at 25:24-27:12).

term should be "construed to be consistent" with the express definition of "pharmaceutically effective absorption" found at column 4, lines 59-67 of the '459 patent and column 4, line 64 to column 5, line 5 of the '460 patent, and after discussing the same prosecution history amendment relied upon by Dr. Yates in his declaration, Teva reached the conclusion that:

> the claims should be construed as limited to amounts of chelating compound and risedronate to achieve "pharmaceutically effective absorption," i.e., "an amount of a chelating compound high enough to significantly bind the metal ions and minerals in food but low enough not to significantly alter absorption of risedronate as compared to absorption in the fasted state" and where "absorption is similar with or without food." See, e.g., column 4, lines 59-67 of the '459 patent and column 4, line 64 to column 5, line 5 of the '460 patent.

(Davis Decl. II, Exh. 10 at 7). Tellingly, nowhere did Teva conclude that "pharmaceutically effective absorption" should be construed to mean "fed exposure of bisphosphonate within about 50% of fasting exposure."

4. There Is Nothing Ambiguous About Warner Chilcott's Proposed Construction

Contrary to Defendants' assertion, there is no infirmity in construing the term "pharmaceutically effective absorption" in accordance with the entire definition provided by the applicants in the '459 and '460 patents. (Def. Br. at 18-22). In the context of the claimed inventions, it is a logical and straightforward result.

Defendants' expert Dr. Yates concedes that, even under fasting conditions, bisphosphonates are poorly absorbed. (Yates Decl. ¶ 22). However, in the presence of food, absorption of bisphosphonates is "virtually negligible," due in part to interactions between bisphosphonates and calcium and other multivalent cations present in food. (Yates Decl. ¶ 20). The chemical compound EDTA was known to act as an absorption enhancer, i.e., it can increase the absorption of certain pharmaceuticals. But simply increasing the absorption of a

pharmaceutical, such as risedronate, does not solve the food effect. To the contrary, it could make the problem worse. The inventors overcame the food effect problem in a unique way, by adding EDTA in combination with risedronate in an amount "high enough to significantly bind metal ions and minerals in food," i.e., thus preventing absorption of the bisphosphonate from becoming "virtually negligible" in the presence of food, "but low enough not to significantly alter absorption of the bisphosphonate as compared to absorption in the fasted state," i.e., to limit its action as an absorption enhancer. (Davis Decl. I, Exh. 1, '459 patent, col. 4, ll. 59-67; Exh. 2, '460 patent, col. 4, l. 64 – col. 5, l. 5). By using the claimed inventions, the risedronate absorption "is similar with or without food." *Id*. There is nothing ambiguous about this definition. To the contrary, as explained above, that is how Teva understood this term after analyzing the intrinsic evidence for the '459 and '460 patents in 2011.

Defendants' speculation that Warner Chilcott's motive for construction of the phrase "pharmaceutically effective absorption" is driven by a concern over Brazilian patent application BR2001-06601 is misplaced and has no bearing on how to properly construe this term. (Def. Br. at 18-19). The claims are to be construed separate and apart from infringement or validity issues. *See Phillips*, 415 F.3d at 1327-28 (invalidity considerations have "no applicability" to claim construction); *Nazomi Commc'ns, Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1368-69 (Fed. Cir. 2005) ("courts should not rewrite claims to preserve validity").

Moreover, the Defendants are wrong. The claims of the '459 and '460 patents, as well as the subsequent '989 patent, were all allowed after the Examiner considered that same Brazilian reference. In allowing the '989 patent claims, the Examiner specifically remarked that the Brazilian reference "teaches away from using EDTA":

> The following is an examiner's statement of reasons for allowance: the closest prior art include a Brazilian patent application BR2001-

> 06601, which disclosed that the JANNER et al. reference teaches way from using EDTA to improve absorption of bisphosphonate. BR2001-06601 further teaches that the EDTA can be used to improve absorption of bisphosphonate if an enteric coating is applied. BR2001-06601 suggested that risedronate can be the bisphosphonate. However, BR2001-06601 does not provide any data that the absorption of bisphosphonate did improve. Additionally, other prior art also teaches away from using EDTA clinically . . . . Thus, in light of all the evidences that teach away from using EDTA and the lack of data in the BR2001-06601 reference, BR2001-06601 did not provide one skilled in the art to have any reasonable expectation of success to use risedronate with EDTA and an enteric coating to improve absorption.

(Patunas Decl. Exh. F at WTS0010593, emphasis added).

There also is no merit to Defendants' arguments that referencing "an amount" of the chelating agent in the definition of "pharmaceutically effective absorption" would: (1) render the recited amounts of EDTA claimed superfluous or (2) be improper because it is not the only factor that determines how much risedronate is absorbed. (Def. Br. at 20-22). First, the claims of the '459 and '460 patent refer to ranges of EDTA and risedronate that can be used because the amount of EDTA needed to achieve "pharmaceutically effective absorption" will vary depending, among other things, on the amount of risedronate employed and the specific portion of the lower GI tract where delivery of the chelating agent and/or bisphosphonate active ingredient is desired. (Davis Decl. I, Exh. 1, '459 patent, col. 9, ll. 9-15; Exh. 2, '460 patent, col. 7, ll. 37-43). Thus, the inclusion of a reference to "an amount of chelating agent" is not superfluous in the '459 and '460 patent claims reciting specific amounts. Second, regardless of whether one varies the rate and site of the release of the risedronate in the GI tract, "pharmaceutically effective absorption" requires an amount of EDTA be present to achieve that result.

B. "Oral dosage form" ('989 Patent, Claims 1-9, 12, 14-22, 25 and 27)

Defendants' expert, Dr. Yates, testified that the ordinary meaning of the term "oral dosage form" to a person of skill in the art would be "a term used in the art to identify any form, particularly fixed dose forms, of any pharmaceutical agent that's designed to be taken by mouth." (Davis Decl. II, Exh. 9, Yates Tr. at 273:14-274:3; *see also* Davis Decl. II, Exh. 11, Elder Tr. at 262:7-12). Consistent with that ordinary meaning, the '989 specification defines the term "oral dosage form":

> The term "oral dosage form," as used herein, means any pharmaceutical composition intended to be administered to the lower gastrointestinal tract of a human or other mammal via the mouth of said human or other mammal.

(Davis Decl. I, Exh. 3, '989 patent, col. 5, ll. 4-7).

The only difference between Dr. Yates's ordinary meaning and the '989 specification's definition is that the specification specifies that the oral dosage form is "intended to be administered to the lower gastrointestinal tract." Thus, Dr. Yates's definition is consistent with the '989 patent definition, and the Court should adopt Warner Chilcott's proposed definition. *Phillips*, 415 F.3d at 1316 ("[T]he inventor's lexicography governs . . . the inventor's intention, as expressed in the specification, is regarded as dispositive.").

1. Defendants' Proposed Construction Should Be Rejected

In contrast, Defendants' proposed construction of the term "oral dosage form" – "a pharmaceutical composition containing a safe and effective amount of a chelating agent that exhibits fed exposure of risedronate within about 50% of fasting exposure" – deviates from the meaning of that term as defined in the '989 specification.

First, Defendants' proposed definition of "oral dosage form" does not even require that the pharmaceutical composition be taken by mouth, even though both Dr. Yates's ordinary meaning and the definition in the '989 specification both expressly contain that requirement.

Second, there is no basis for the Defendants to add the language "containing a safe and effective amount of a chelating agent that exhibits fed exposure of risedronate within about 50% of fasting exposure" into this claim term. Nowhere does the specification define this term in reference to "a safe and effective amount of a chelating agent." Even Defendants' expert, Dr. Yates, disagrees with Defendants' proposed construction, opining that this term should not be construed in reference to "an amount of a chelating agent" because it "clearly refers to a composition," and "there is no need for the skilled person to read into the words 'an oral dosage form' 'an amount of chelating agent' because that is covered in . . . the comprising elements that follow thereon." (Davis Decl. II, Exh. 9, Yates. Tr. at 279:2-280:5). It is improper to read limitations into the claim without a clear and unambiguous disclaimer of claim scope. *Phillips*, 415 F.3d at 1316.

While admitting that the claims of the '989 patent do not contain the phrase "pharmaceutically effective absorption," Defendants seek to bootstrap that limitation into the definition of "oral dosage form" of the '989 patent claims on the basis that it is an "essential element" of the invention. The authority cited by Defendants, *MBO Labs, Inc. v. Becton Dickinson & Co.*, 474 F.3d 1323 (Fed. Cir. 2007), does not support Defendants' position. In *MBO*, the Federal Circuit agreed that the patentee had indicated that an essential feature of the claimed invention was immediate needle safety upon removal from the patient and it was therefore appropriate to construe the claims containing the term "immediately" to ensure they require that feature. *Id.* at 1330. However, the Federal Circuit reversed the district court's

construction of claims to require that feature where the claims did not contain the word "immediately." *Id.* at 1330-31. The same analysis applies here.

Also misplaced is Defendants' reliance on *Hakim v. Cannon Avent Grp., PLC*, 479 F.3d 1313 (Fed. Cir. 2007), for the proposition that statements made during the prosecution histories of the '459 and '460 patents somehow support including the term "pharmaceutically effective absorption" in the definition of "oral dosage form" in the '989 patent. (Def. Br. at 25). In *Hakim*, the patentee changed the term "slit" to "opening" in a continuation application but had disclaimed anything broader than a "slit" in an earlier application, and thus was held bound to the disclaimer. *Hakim*, 479 F.3d at 1316. That is not the case here; in fact Defendants admit the '989 patent omits the term "pharmaceutically effective absorption." Directly on point is *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173 (Fed. Cir. 2006). Similar to the Defendants' argument here, in *Ventana* the alleged infringer argued that the inventors disclaimed claim scope in a subsequent application by distinguishing prior art in an earlier application containing claims requiring a reagent to be "dispensable directly to a sample" because the prior art lacked that capability. *Id*. at 1182. In rejecting that argument, the Federal Circuit stated that "the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendent patent uses different language." *Id*. Accordingly, the Federal Circuit held that because the subsequent application used different language, i.e., they did not require the reagent to be "dispensable directly to a sample," the alleged disclaimer did not apply to the claims. *Id*.

Finally, Defendants improperly suggest that construing the phrase "oral dosage form" without adding the limitation "having pharmaceutically effective absorption" renders the claims invalid under 35 U.S.C. § 112 for lack of written description. (Def. Br. at 22-23). Defendants are wrong; the '989 specification provides adequate written description for the claimed delayed

release oral dosage forms containing about 35 mg of risedronate and about 100 mg of EDTA (*See, e.g.*, Davis Decl. I, Exh. 3, '989 patent, Examples I, III, XII, XIX). In any event, Defendants' invalidity assertions are premature, and have no place during claim construction. In *Rhine v. Casio, Inc.*, the Federal Circuit rejected the defendant's attempt to argue that a claim was invalid based on the Federal Circuit's claim construction, stating:

> This argument is premature. [The Defendant] cannot avoid a full-blown validity analysis by raising the specter of invalidity during the claim construction phase.

Rhine v. Casio, Inc., 183 F.3d 1342, 1346 (Fed. Cir. 1999).

2. <u>Defendants' Proposed Construction Is Not Reasonable</u>

Defendants' purported "reasonable" construction based on the specification is wrong. (Def. Br. at 25-26). Starting with the definition of "oral dosage form" in the '989 specification, Defendants then incorporate definitions and discussions of four other terms to arrive at their definition. Specifically, Defendants refer to: (1) the term "pharmaceutical composition," (2) a description of "a safe and effective amount of chelating agent," (3) a discussion of the meaning of "without significantly affecting absorption of the bisphosphonate had no food been present," and (4) ending with the phrase "pharmaceutically effective absorption." (Def. Br. at 25-26). Only by combining the meaning of those phrases do Defendants reach their definition. The weakness of Defendants' argument is shown by the fact that they selectively use definitions from those four terms, while ignoring definitions of other terms within those same phrases. Defendants' contrived result speaks volumes and should be rejected on that basis alone.

Moreover, Defendants' leap from the term "pharmaceutical composition" to "a safe and effective amount of a *chelating* agent" is baseless. The term "pharmaceutical composition" is described in the '989 patent as "an oral dosage form comprised of *a safe and effective amount of a bisphosphonate active ingredient* and one or more pharmaceutically-acceptable excipients

including at least one chelating agent." (Davis Decl. I, Exh. 3, '989 patent, col. 5, ll. 34-38) (emphasis added). The "safe and effective amount" in the phrase is clearly referring to the bisphosphonate active ingredient, not the chelating agent which is required to proceed to Defendants' next step in their analysis. Defendants' expert, Dr. Yates, testified during cross examination that the statement "safe and effective amount" "obviously is referring to the amount of a bisphosphonate" (Davis Decl. II, Exh. 9, Yates. Tr. at 297:4-299:5),[4] not the chelating agent as Defendants assert. Defendants' construction is contrary to the testimony of their own expert and should be rejected.

Defendants' position here is in stark contrast to Watson's position in its Notice Letter. Defendant Watson provided the following discussion regarding construction of the '989 patent claims:

> The specification of the '989 patent provides no relevant discussion of the meaning of the claim terms. Accordingly, the specification and claims alone must provide the basis for interpretation of the intended meaning of the claims. Based upon the specification, the terms in the claims of the '989 patent should receive their normal and customary meaning in the chemical/pharmaceutical arts as commonly understood by one of ordinary skill in the art.

(Davis Decl. II, Exh. 12 at 5). Nowhere did Watson (or the other Defendants in their '989 patent Notice Letters) propose the construction of "oral dosage form" that it now asks the Court to adopt.

[4] On redirect, Dr. Yates, at the suggestion of Defendants' attorneys during a 20 minute break, sought to "clarify" that he believes the phrase "safe and effective" in the term "pharmaceutical composition" refers both to the amount of a bisphosphonate active ingredient and to one of more of the pharmaceutically acceptable excipients, including at least one chelating agent. (Davis Decl. II, Exh. 9, Yates Tr. at 334:13-338:5). That manufactured testimony, which is clearly at odds with a plain reading of the definition of "pharmaceutical composition," is not credible.

C. "A delayed release mechanism" ('459 Patent, Claims 1-7; '989 Patent, Claims 1-9, 12, 14-22, 25 and 27)

The phrase "a delayed release mechanism" in the '459 and '989 patents should be construed to mean "a mechanism designed to effect release at some generally predictable location in the lower GI tract more distal to that which would have been accomplished without the mechanism."

Defendants allege "delayed release mechanism" should be construed as "***one or more excipients that will delay release*** of the bisphosphonate and chelating agent until the oral dosage form has reached the lower GI tract." But, nowhere do the patent specifications or claims require limiting the "mechanism" to those containing "one or more excipients that will delay release."

The '459 and '989 patents state that the oral dosage forms of the inventions comprise a "means for effecting delayed release." (Davis Decl. I, Exh. 1, '459 patent, Abstract; col. 1, ll. 16-17; Exh. 3, '989 patent, Abstract; col. 1, ll. 19-20). The '459 and '989 patent specifications further explain:

> Various means for targeting release of the bisphosphonate and the chelating agent in the lower GI tract are suitable for use in the present invention. Non-limiting examples of means for delivery to the lower GI tract include pH triggered delivery systems, dose forms from which the release is triggered by the action of bacterial enzymes, and time dependent delivery systems.

(Davis Decl. I, Exh. 1, '459 patent, col. 10, ll. 42-48; Exh. 3, '989 patent, col. 10, ll. 43-49). Thus, the '459 and '989 patents clearly contemplate that the mechanism for achieving delayed release is not limited to formulations which employ "one or more excipients" to achieve delayed release. A POSA would have understood the term "mechanism" to be **any** means by which delayed release might be effected.

Dr. Elder's declaration asserts that the '459 and '989 patents only disclose examples of formulations "made up of one or more conventional pharmaceutical excipients in combination

with [a] bisphosphonate." (Elder Decl. ¶ 35). Dr. Elder's testimony that "delayed release mechanism" is limited to one or more excipients is, therefore, inconsistent with the specification (as shown above), and should be rejected. *Phillips*, 415 F.3d at 1318*; Vitronics*, 90 F.3d at 1582. Moreover, at deposition, Dr. Elder testified he did not know how delayed release delivery was achieved in Example XIX, including whether a mechanical capsule had been used. (Davis Decl. II, Exh. 11, Elder Tr. at 204:24-205:19). And he admitted he was not an expert in the area of what methods could have been used to achieve delivery sites such as the jejunum in Example XIX. (Davis Decl. II, Exh. 11, Elder Tr. at 205:9-19). Defendants' reliance on such conclusory expert testimony is unhelpful to the Court and should be given no weight. *Phillips*, 415 F.3d at 1318.

Defendants also argue that "delayed release" is achieved by "formulating" the risedronate and EDTA," then improperly construe the term "formulation," to arrive at their definition. (Def. Br. at 31-34). This is another example of Defendants' reliance on unsupported conclusory opinion of its expert Dr. Elder. Dr. Elder provides no support for his definition of "formulation." (Davis Decl. II, Exh. 11, Elder Tr. at 153:6-154:9; 156:3-157:20). As explained in Warner Chilcott's opening brief, a POSA would understand that mechanisms for delaying release are not limited to only those containing "one or more excipients to delay release," but would include, for example, the use of an Enterion™ capsule, a mechanical device that releases the components of its capsule at desired sites, described in Warner Chilcott's Provisional Application No. 60/573,881. (Warner Chilcott Br. at 14). Defendants candidly admit that their construction is purposefully designed to exclude such mechanical devices that release a drug into the GI tract. (Def. Br. at 34). Defendants, however, offer no reason based on the intrinsic record why that should be the case – their expert, Dr. Elder, could not preclude the possibility that formulations

of Example XIX of the '459 patent employed mechanical capsules (Davis Decl. II, Exh. 11, Elder Tr. at 204:24-205:19), and in fact they did.

Defendants' argument that the patents limit the mechanisms by which delayed release is achieved because the specifications discuss embodiments containing delayed release excipients for use in the claimed oral dosage forms is mistaken. It is improper to read limitations from the specification into claims, where, as here, the claim language is broader than the embodiments in the patent. *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment").

The doctrine of claim differentiation also refutes Defendants' position. This doctrine states "that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope, [which] . . . normally means that limitations stated in dependent claims are not to be read into the independent claim from which they depend." *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 972 (Fed. Cir. 1999) (internal citations omitted). Defendants argue that the description in the '459 and '989 patents of pH-, time- or bacterial enzyme-dependent means of achieving delayed release limits the "delayed release mechanism" to only those employing "delayed release excipients." However, independent claim 1 of the '459 patent claims an oral dosage form with, *inter alia*, a "delayed release mechanism." (Davis Decl. I, Exh, 1, '459 patent, col. 38, ll. 25-32). Dependent claim 3 narrows the "delayed release mechanism" to one "selected from the group consisting of pH triggered delivery systems, bacterial enzyme triggered delivery systems, time dependent delivery systems and combinations thereof." (Davis Decl. I, Exh. 1, '459 patent, col. 38, ll. 35-39). By definition, claim 1 should not be construed to be as limited as dependent claim 3. The doctrine of claim differentiation is

"at its strongest" when "the sole difference between the independent claim and the dependent claims is the limitation that one party is trying to read into the independent claim." *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1361 (Fed. Cir. 2012) (citations omitted). Defendants' claim construction would eliminate the difference between claim 1 and claim 3, which is improper.

D. "An enteric coating which provides for release" ('459 Patent, Claims 8-16, and 21-22) and "pH dependent enteric coating" ('989 Patent, Claims 3-9, 12 and 14)

The term "an enteric coating which provides for release" in the '459 patent and the term "pH dependent enteric coating" in the '989 patent should be construed to mean "a coating comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the contents of a core. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble at pH 5.5 or higher." (Warner Chilcott Br. at 14).

Defendants agree that its proposed construction – "a pH-triggered coating that will delay release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine" – is consistent with Warner Chilcott's construction, and its only apparent disagreement is that Warner Chilcott's construction does "not make clear that release commences in the small intestine." (*See* Def. Br. at 36). Defendants' suggestion that these claim terms should be construed to require "that release commence in the small intestine" is wrong and unnecessary.

Proof that the term "an enteric coating which provides for release" and "pH dependent enteric coating" should not be construed to require "that release commence in the small intestine" is expressly found by reference to the language of the claims where these terms appear. The context of surrounding words of a claim must be considered in construing the meaning of claim terms. *Phillips*, 415 F.3d at 1314. Independent claim 8 of the '459 patent, reciting the

phrase "an enteric coating which provides for release," clearly specifies that release occur "in the **lower gastrointestinal tract** of a mammal." (Davis Decl. I, Exh. 1, '459 patent, col. 38, ll. 55-57) (emphasis added).[5] Similarly, dependent claim 3 of the '989 patent, reciting the phrase "pH dependent enteric coating," also specifies delivery "to the **lower GI tract**." (Davis Decl. I, Exh. 3, '989 patent, col. 38, ll. 6-8, 12-13) (emphasis added).[6] Construing the terms "an enteric coating which provides for release" and "pH dependent enteric coating" as requiring release only in the small intestine is nonsensical because the claims of the '459 and '989 patent each specifically state that release or delivery can occur in the lower GI tract, i.e., the small and/or large intestine. (*See e.g.*, Davis Decl. I, Exh. 1, '459 patent, col. 38, ll. 25-32; Exh. 3, '989 patent, col. 38, ll. 2-8). Moreover, because other portions of the claims expressly specify where the contents of the oral dosage forms are to be released or delivered, inclusion of such a requirement in these terms is wholly unnecessary.

The specifications of the '459 and '989 patents also do not support Defendants' attempt to construe these two terms as requiring "release of the bisphosphonate and chelating agent until the oral dosage form has reached the small intestine." The '459 and '989 patents clearly state that "release will be accomplished at some generally predictable location in the lower GI tract". (Davis Decl. I, Exh. 1, '459 patent, col. 10, ll. 17-25; Exh. 3, '989 patent, col. 10, ll. 18-26). Defendants' expert, Dr. Elder, agreed that the enteric coatings disclosed in the '459 and '989 patents, such as Eudragit® S, afford release in the terminal ileum (a region of the small intestine)

[5] The '459 patent specification states that the "lower gastrointestinal tract," includes "the small intestine and the large intestine." (Davis Decl. Exh. 1, '459 patent, col. 5, ll. 25-27).

[6] To the extent Defendants' position is meant to suggest a requirement that the enteric coatings of the '459 and '989 do not begin to dissolve and release until the dosage form reaches the small intestine, that requirement is wrong. For example, dependent claim 9 of the '989 patent, which depends on independent claim 1, claims an oral dosage form wherein "the pH dependent enteric coating does not entirely dissolve or disintegrate until the dosage form enters the small intestine." (Davis Decl. I, Exh. 3, '989 patent, col. 38, ll. 29-32).

as well as in the large intestine. (Davis Decl. II, Exh. 11, Elder Tr. at 190:5-191:5). Other sections of the specification of the '459 and '989 patents confirm there is no requirement that release begin to occur in the small intestine:

- In the description of "pH Triggered Delivery Systems," the specification states "delayed release of the pharmaceutical composition is achieved by coating the…with a substance which is pH dependent, i.e., broken down or dissolves at a pH which is generally present in the **lower GI tract**." (Davis Decl. I, Exh. 1, '459 patent, col. 10, l. 66 – col. 11, l. 6 (emphasis added); *see also* Exh. 3, '989 patent, col. 10, l. 67- col. 11, l. 6).

- "It is expected that any anionic polymer exhibiting the requisite pH-dependent solubility profile can be used as an enteric coating in the practice of the present invention to achieve delivery of the bisphosphonate and chelating agent to the **lower GI tract**." (Davis Decl. I, Exh. 1, '459 patent, col. 12, ll. 10-14 (emphasis added); *see also* Exh. 3, '989 patent, col.12, ll. 12-16).

- Coating thickness [of the enteric coating] must be sufficient to ensure that the oral dosage form remains essentially intact until the desired site of delivery in the **lower GI tract** is reached. (Davis Decl. I, Exh. 1, '459 patent, col. 13, ll. 2-4 (emphasis added); *see also* Exh. 3, '989 patent, col. 13, ll. 4-6; Davis Decl. II, Exh. 11, Elder Tr. at 261:15-23).

There is no support for Defendants' construction which limits release to the small intestine, nor is there any reason to include such a requirement.

E. "A delayed release mechanism to immediately release the risedronate" ('460 Patent, Claims 1-7, and 10-14) and "an enteric coating which provides for immediate release" ('460 Patent, Claims 8-9, 15-20, and 27-28)

For the reasons explained in Warner Chilcott's opening brief, the phrase "a delayed release mechanism to immediately release the risedronate" in the '460 patent should be construed to mean "a mechanism designed to effect release of risedronate at some generally predictable location in the small intestine in an immediate release fashion." (Warner Chilcott Br. at 10-11). In addition, the term "an enteric coating which provides for immediate release" in the '460 patent should be construed to mean: "A coating comprised of one or more polymers

designed to dissolve in a pH dependent manner and which effects release of the contents of a core in an immediate release fashion as the coating dissolves. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble between about pH 5.5 and about pH 6.5." (Warner Chilcott Br. at 11-13).

1. "A delayed release mechanism to immediately release the risedronate"

Defendants' proposed construction of "a delayed release mechanism to immediately release the risedronate" contains a requirement that the "mechanism" be "one or more excipients that will delay release." For the reasons explained in section C, *supra*, there is no support for Defendants' attempt to define the construction of a "delayed release mechanism" to "one or more excipients that will delay release." Like the '459 and '989 patents, the '460 patent specification clearly states that "various means for targeting release of risedronate and the chelating agent in the small intestine are suitable for use in the present invention" (Davis Decl. I, Exh. 2, '460 patent, col. 8, ll. 63-65).

As to the remainder of the definition of "a delayed release mechanism to immediately release the risedronate," there does not appear to be significant disagreement between the parties. For example, the parties appear to agree that release of risedronate occurs in the small intestine. (Compare Warner Chilcott's definition, "release of risedronate at some generally predictable location in the small intestine," with Defendants' proposed language, "release of the bisphosphonate and chelating until the oral dosage form has reached the small intestine."[7]) With respect to the "immediately release" limitation, Warner Chilcott proposes that this portion of the definition be construed simply to mean "in an immediate release fashion" whereas Defendants

[7] Unlike the '459 and '989 patents which, as explained *supra*, specify the site of release of as the lower GI tract, the '460 patent specifies that release occur in the small intestine. (Davis Decl. I, Exh. 2, '460 patent, col. 24, ll. 23-31).

suggest this limitation be construed as "all of the bisphosphonate and chelating agent will be released from the oral dosage form within 60 minutes when measured by a standard USP method." Although Warner Chilcott believes its proposed construction of this portion of the definition is proper based on the intrinsic evidence, Warner Chilcott believes a compromise construction of "in an immediate release fashion, i.e., all of the bisphosphonate will be released from the oral dosage form within 60 minutes when measured by a standard USP dissolution method" is reasonable.

2. "An enteric coating which provides for immediate release"

With respect to the phrase "an enteric coating which provides for immediate release," the parties' competing definitions appear to have more similarities than differences. Although Warner Chilcott believes its proposed definition of this term is correct, as explained in its opening brief, Warner Chilcott believes its proposal based on both parties' suggested language (which Defendants rejected without explanation) would be an acceptable compromise:

> A coating comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the bisphosphonate and chelating agent in the small intestine in an immediate release fashion, i.e. all of the bisphosphonate and chelating agent will be released from the oral dosage form within 60 minutes when measured by a standard USP dissolution method. An enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble between about pH 5.5 and about pH 6.5.

(Warner Chilcott Br. at 12).

Warner Chilcott's proposed construction of the terms "a delayed release mechanism to immediately release the risedronate" and "an enteric coating which provides for immediate release" should be adopted as the correct one. Alternatively, the Court should adopt Warner Chilcott's proposed compromise constructions of these terms.

F. "EDTA" ('459 Patent, Claims 1-7; '460 Patent, Claims 1-7, and 10-14) and "EDTA or a pharmaceutically acceptable salt thereof" ('989 Patent, Claims 1-9, 12, 14-22, 25 and 27)

Warner Chilcott proposes that: (1) the term "EDTA" (in the '459 and '460 patents) be construed to mean "the chelating agent ethylenediamine tetraacetic acid and its salts," and (2) the term "EDTA or a pharmaceutically acceptable salt thereof" (in the '989 patent) be construed to mean "the chelating agent ethylenediamine tetraacetic acid and its salts acceptable for pharmaceuticals, such as disodium EDTA."

The primary substantive dispute between the parties is whether these two phrases should include the words "the chelating agent" as Warner Chilcott proposes.[8] As explained in Warner Chilcott's opening brief, the specifications of the three patents and their file histories confirm the use of EDTA (and its salts) as a chelating agent. (Warner Chilcott Br. at 16-17, 19-20). Defendants do not disagree. Defendants acknowledge that the specifications of the patents-in-suit identify EDTA (and its salts) as a "chelating agent." (Def. Br. at 29; *see also* Davis Decl. II, Exh. 11, Elder Tr. at 149:13-21). Defendants also correctly note that during prosecution of the '459 and '460 patents, the examiner replaced the phrase "a chelating agent" in the claims with the term "EDTA" (Def. Br. at 30) – a clear acknowledgement that the term EDTA was a specifically claimed chelating agent. Accordingly, it is clear that the definitions of "EDTA" and

[8] The parties agree that, as used in the '459 and '460 patents, "EDTA" refers to the chemical compound "ethylenediamine tetraacetic acid and its salts." (Warner Chilcott Br. at 16, 19; Def. Br. at 27-28). In addition, the language "suitable for use in a drug product" in Defendants' definition of the '989 patent's phrase "EDTA or a pharmaceutically acceptable salt thereof" appears consistent with Warner Chilcott's proposed language of "acceptable for pharmaceuticals" in its definition. (Warner Chilcott Br. at 19; Def. Br. at 28). Defendants did not comment on Warner Chilcott's proposed language "such as disodium EDTA" as part of the definition of "EDTA or a pharmaceutically acceptable salt thereof" in the '989 patent, but Defendants concede that disodium EDTA is a particular salt of EDTA covered by this language. (Def. Br. at 29).

"EDTA or pharmaceutically acceptable salt thereof" as used in the patents should be construed as referring to "the chelating agent" ethylenediamine tetraacetic acid and its salts.

G. "pH dependent enteric coating of the granules" ('989 Patent, Claims 15-22, 25 and 27)

The phrase "pH dependent enteric coating of the granules" in the '989 patent should be construed as "the pH dependent enteric coating that contains the granules."

Defendants seek to limit the construction of this term to "coating individual granules containing the risedronate and EDTA with pH-triggered coating." (Def. Br. at 39). Defendants' construction, which selectively relies on one of the embodiments of the patent, is improper. *See Superguide Corp.*, 358 F.3d at 875. There is no support in the patent specification for such a limiting construction and none should be given.

To the contrary, the specification of the '989 patent states that "[t]he oral dosage form can be in the form of an ***enteric coated compressed tablet made of granules*** or particles of active ingredient" (Davis Decl. I, Exh. 3, '989 patent, col. 11, ll. 56-60, emphasis added); "[f]or purposes of the present invention, the delivered form can be in the form of ***a compressed tablet containing granules*** or particles of a bisphosphonate and a chelating agent" (Davis Decl. I, Exh. 3, '989 patent, col. 5, ll. 7-10, emphasis added); and "[t]he solid oral dosage form may be in the form of a ***coated compressed tablet which contains*** particles or ***granules*** of the bisphosphonate active ingredient and the chelating agent" (Davis Decl. I, Exh. 3, '989 patent, col. 13, ll. 7-9, emphasis added). Defendants' expert Dr. Elder admitted that the specification of the '989 patent disclosed that tablets can be enteric coated and that compressed tablets can contain granules. (Davis Decl. II, Exh. 11, Elder Tr. at 262:13-20; 268:9-269:15). Clearly, the '989 patent specification does not limit its teaching only to granules that are "individually" coated, but rather also teaches enterically coating a compressed tablet containing the granules.

III. CONCLUSION

For the foregoing reasons and the reasons set forth in its opening claim construction brief, Warner Chilcott respectfully requests that the Court adopt Warner Chilcott's proposed constructions of the claim terms.

January 11, 2013

Respectfully submitted,

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